

JUL 03 2013

7. 510(K) SUMMARY – Device Modification**Introduction:**

This document contains the 510(k) Summary for the Cyber Tm Family.
The content of this summary is based on the requirements of 21 CFR 807.92(c).
This is the first submission for the Cyber Tm Family

**Applicant /
Manufacturer
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Date Prepared: November 20th, 2012
Device Name: Cyber Tm Family
Classification: Class II
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology.
Regulation Number: 21 CFR 878.4810
Product Code: GEX
Basis for Submission: Technology, Engineering, and Performance Changes

Legally Marketed Device

The Cyber Tm Family is claimed to be substantially equivalent to these legally marketed devices:

- Cyber Tm 120 of the Cyber Surgical Laser Family (K090962) – Quanta System SpA
- Cyber Tm 150 (K102749) – Quanta System SpA
- RevoLix Family (K110941) – AllMed System Inc.

Performance Standards:

There are no mandatory performance standards for this device.

General Device Description (unmodified predicate devices vs new modified devices):

The Cyber Tm Family is laser surgical instrument for use in general and plastic surgery and in dermatology (GEX).

In the Cyber Tm Family is installed a single Tm:YAG Laser Source with CW emission at 2.01µm with adjustable power from 5 W to the maximum output power (as given below). The laser radiation is delivered to the tissue to be treated through fiber optics.

The Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including:

Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

Note: the Cyber Tm 180 and Cyber Tm 200 are only approved for the treatment of BPH when used at power levels greater than 150W.

The Cyber Tm Family has the following models (and related main characteristics):

Models	Type of laser	Wavelength	Min Power	Max Power
Cyber Tm 120 (unmodified) predicate device	CW Tulum:YAG	2.010 µm	5 W	120 W
Cyber Tm 150 (unmodified) predicate device	CW Tulum:YAG	2.010 µm	5 W	150W
Cyber Tm 180 (new) modified device	CW Tulum:YAG	2.010 µm	5 W	180 W
Cyber Tm 200 (new) modified device	CW Tulum:YAG	2.010 µm	5 W	200 W

The first two models of the Cyber Tm Family, the Cyber Tm 120 and Cyber Tm 150, have been already cleared and represent the unmodified devices (Legally Marketed Devices).

The other two, the Cyber Tm 180 and Cyber Tm 200, are the derived from the previous ones.

All models share the same structure, the same components and the same software. The differentiation of the models derives only from the factory set of the maximum output power, as detailed in the next section.

Description of the modification:

The first two models of the Cyber Tm Family, the Cyber Tm 120 and Cyber Tm 150, have been already cleared and represent the unmodified devices (Legally Marketed Devices).

The other two, the Cyber Tm 180 and Cyber Tm 200, are the derived from the previous ones.

The modification of the devices is limited to the Tm:YAG Laser Source that is installed inside Cyber Tm Family.

So all models of the Cyber Tm Family share the same structure, the same components and the same software. The differentiation of the models derives only from the factory set of the maximum output power of the laser resonator.

Summary of Performance and basic Safety testing:

The Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories have been tested in accordance with:

- IEC 60601-1:2005
- IEC 60601-1-2:2005
- IEC 60601-1-4: 1996 (First Ed.) -+ Am.I: 1999 (Consolidated 1.1 Ed.)
- for use with IEO 60601-1 (1988), Amts 1 (1991) and 2 (1995)
- IEC 60601-2-22:2005
- IEC 60825-1:2007

The Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories comply with European Medical Device 93/42/EEC.

Moreover a specific bench testing was conducted on the proposed Cyber Tm Family devices to support a determination of substantial equivalence to the predicate device. The depth of thermal injury and coagulation were measured and compared to the unmodified predicate devices and did not show significant differences. The ablation depth was also measured and found to be of comparable depth, keeping the same power density through the use of different fiber diameter. Other tissue effects such as carbonization were also found to be comparable.

Indications for Use

The Cyber Tm Family is laser surgical instrument for use in general and plastic surgery and in dermatology (GEX).

In the Cyber Tm Family is installed a single Tm:YAG Laser Source with CW emission at 2010 nm with adjustable power from 5 W to the maximum output power (as given below). The laser radiation is delivered to the tissue to be treated through fiber optics.

The Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including:

Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

Note: The Cyber Tm 180 and Cyber Tm 200 are only approved for the treatment of BPH when used at power levels greater than 150W

The Cyber Tm Family has the following models:

Models	Type of laser	Wavelength	Min Power	Max Power
Cyber Tm 120 (unmodified) predicate device	CW Tulum:YAG	2.010 µm	5 W	120 W
Cyber Tm 150 (unmodified) predicate device	CW Tulum:YAG	2.010 µm	5 W	150W
Cyber Tm 180 (new) modified device	CW Tulum:YAG	2.010 µm	5 W	180 W
Cyber Tm 200 (new) modified device	CW Tulum:YAG	2.010 µm	5 W	200 W

The first two models of the Cyber Tm Family, the Cyber Tm 120 and Cyber Tm 150, have been

already cleared and represent the unmodified predicate devices (Legally Marketed Devices). The Cyber Tm 180 and Cyber Tm 200, are the derived from the previous ones. The *RevoLix Family (K110941)* has been already cleared and is a secondary predicate device (Legally Marketed Devices).

The intended use of the predicate devices (Legally Marketed Devices) are the same as the modified devices.

Substantial Equivalence:

The first two models of the Cyber Tm Family, the Cyber Tm 120 and Cyber Tm 150, have been already cleared and represent the unmodified predicate devices (Legally Marketed Devices). The Cyber Tm 180 and Cyber Tm 200, are the derived from the previous ones. The *RevoLix Family (K110941)* has been already cleared and is a secondary predicate device (Legally Marketed Devices).

All models of the Cyber Tm Family share the same structure, the same components and the same software. The modified devices have the same intended use and the same technological characteristics and principles of operation as the unmodified devices. It has been demonstrated that the modified devices of the Cyber Tm Family are safe and effective as the unmodified devices and the predicate devices.

Thus the modified devices included in the Quanta System Cyber Tm Family are substantially equivalent to the previously legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

Quanta System Spa
% Mr. Maurizio Bianchi
Via IV Novembre N° 116
21058 Solbiate Olona (VA)
Italy

July 3, 2013

Re: K131081

Trade/Device Name: Cyber Tm Family

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general surgery and
plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: June 12, 2013

Received: June 13, 2013

Dear Mr. Bianchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family

Indications for Use:

The Cyber Tm Family (that includes Cyber Tm 120, Cyber Tm 150, Cyber Tm 180 and Cyber Tm 200) and its accessories are intended for use in surgical procedures using open, laparoscopic and endoscopic incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue in use in medical specialties including:
Urology, Gastroenterology, Thoracic and Pulmonary, Gynecology, ENT, Dermatology, Plastic Surgery, General Surgery and Arthroscopy.

Urology:

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral Strictures
- Bladder Neck Incisions (BNI)
- Ablation and resection of Bladder Tumors, Urethral Tumors and Ureteral Tumors.
- Ablation of Benign Prostatic Hypertrophy (BHP).
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostate
- Laser Enucleation of the Prostate
- Laser Ablation of the Prostate
- Condylomas
- Lesions of external genitalia

Note: The Cyber Tm 180 and Cyber Tm 200 are only approved for the treatment of BPH when used at power levels greater than 150W.

Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 C.F.R. 807 Subpart C)

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Neil R Ogden, Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131081

Indications for Use Statement

510(k) Number (if known): K131081

Device Name: **Cyber Tm Family**
Indications for Use: continued

Gastroenterology:

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/Bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non Bleeding Ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and Malignant Neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular Malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric Erosions

Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 C.F.R. 807 Subpart C)

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Division of Surgical Devices

510(k) Number K131081

Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family

Indications for Use: continued

Gynecology:

Open and laparoscopic gynecological surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis):

- Intra-uterine treatment of submucous fibroids
- benign endometrial polyps; and uterine septum by incision, excision, ablation and or vessel coagulation
- Soft tissue excision procedures such as excisional conization of the cervix

ENT:

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft tissue) including:

- Endonasal/sinus Surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal Sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and laryngeal
- Tonsillectomy
- Adenoidectomy

Dermatology and Plastic Surgery:

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue, in therapeutic plastic, dermatologic and aesthetic surgical procedures including:

- Basal Cell Carcinomas
- Lesion of skin and subcutaneous tissue
- Skin tags
- Plantar warts

Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 C.F.R. 807 Subpart C)

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510(k) Number K131081

Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family

Indications for Use: continued

General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesion
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial Nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of Decubitus Ulcer
- Hemorrhoids
- Debridement of Stasis Ulcer

Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 C.F.R. 807 Subpart C)

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Division of Surgical Devices

510(k) Number K131081

Indications for Use Statement

510(k) Number (if known): K131081

Device Name: Cyber Tm Family

Indications for Use: continued

Thoracic and Pulmonary

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) of soft tissue

- Laryngeal lesions
- Airway obstructions including carcinoma
- Polyps and granuloma
- Palliation of obstructing carcinoma of the tracheobronchial tree

Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue):

- Ablation of soft and cartilaginous tissue in Minimal Invasive Spinal Surgery including
- Percutaneous Laser Disc Decompression/Discectomy
- Foraminoplasty
- Ablation and coagulation of soft vascular and non vascular tissue in minimally invasive spinal surgery.

Prescription Use X
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use
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